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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,673	09/17/2007	Robert Danziger	05-159-A	9232

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,673	DANZIGER, ROBERT	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment filed on March 11, 2010 is acknowledged. Claims 14-17 have been withdrawn. Claims 1-13 are under examination in the instant office action.

Applicants' arguments and the declaration under 37 CFR 1.132, filed on March 11, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2004/105751 (filing date: 5/28/2003, hereafter Barone *et al.*).

Barone *et al.* teaches a method of treating hypertension in a mammal, comprising administering an effective amount of PDE4 inhibitor such as rolipram (claims 1, 5, and 7-8). It further teaches the use of PDE4 inhibitor includes veterinary use as well as human use (p10, lines 9-13 and p4, lines 22-24). The subject undergoing the method of the reference implicitly encompasses patients suffering from all types of hypertension including salt-sensitive hypertension. Furthermore, the patient population of the instant invention substantially overlaps with that of the reference as evidenced by Weinberger *et al.* (Hypertension, 8 (Suppl II): II-127-II-134, 1986), which teaches that more than 51% of patients with hypertension are classified as salt-sensitive, 16% as salt resistant, and the remaining as having an intermediate response (abstract and pII-129, table 1). Thus the teaching of treating hypertension with rolipram reads on the instant claims.

The PDE inhibitor used in the method of the reference is the same compound as the instant application (rolipram), thus it meets limitations recited in claims 2-10. Furthermore, Applicant states that claims 1-13 reads on the elected species, rolipram, thus rolipram as PDE4 inhibitor must have the properties recited in claims 2-10.

As such, the instant claims are anticipated by Barone *et al.*

Response to Applicants' argument:

Applicants' arguments and declaration under 37 CFR 1.132 were fully considered but are unpersuasive.

Applicants argued that Barones does not explicitly or implicitly teach a method of reducing hypertension using a PDE inhibitor. On the contrary to Applicant's assertion, Barone *et al.* explicitly teach a method of treating hypertension comprising administering a PDE inhibitor

such as rolipram. The reference teaches a generic method of reducing cardiovascular pathology in a mammal comprising administering an effective amount of a PDE inhibitor and further identifies the mammal suffering from hypertension as a target patient population in need of administering PDE inhibitor. See the following claims of WO 2004/105751, which were cited for anticipatory teaching (claims 1, 5, 7-8) :

1. A method of reducing cardiovascular pathology in a mammal, comprising administering an amount effective for reducing said cardiovascular pathology with a phosphodiesterase 4 (PDE4) inhibitor.

5. The method of claim 1 wherein the mammal suffering from hypertension.

6. The method of claim 1, wherein the mammal is suffering from arteriosclerosis.

7. The method of claim 1, wherein the PDE4 inhibitor is PDE4 specific inhibitor.

8. The method of claim 7, wherein the PDE4 specific inhibitor is rolipram.

Furthermore, Barone *et al.* teaches the administration of the same PDE inhibitor (rolipram) for the same patient population (i.e. mammal suffering from hypertension) as the instant invention, thus reducing hypertension necessarily occurs when the method of the reference is practiced.

In response to the argument that Barone *et al.* do not enable one of ordinary skill in the art carry out the claimed invention, a disclosure is enabled if a person of ordinary skill could make and use it without undue experimentation. Undue experimentation is determined in light of the factors enumerated in MPEP 2164.01. Applicants have not analyzed these factors, but instead

have made a blanket conclusory statement that the prior art is not enabled. This argument therefore amounts to a mere allegation of patentability, which cannot be persuasive. As stated in the last office action, Barone *et al.* teaches the use of the same PDE inhibitor (rolipram) for the same method (i.e., treating hypertension by administering an effective amount of a PDE inhibitor) as the instant invention. If the instant invention is enabled, so did the reference. In addition, a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. *In re Boe*, 355 F.2d 961, 148 U.S.P.Q. 507 (C.C.P.A. 1966). *In re Chapman*, 357 F.2d 418, 148 U.S.P.Q. 711 (C.C.P.A. 1966). In this case, Barones *et al.* as a whole provide sufficient disclosure for enablement needed to anticipate the present claims to those of ordinary skill in the art. Finally, when the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). However, Applicant did not provide a preponderance of the evidence in order to rebut the presumption of operability. Furthermore, the declaration stating that a drug that is purportedly effective in treating hypertrophy does not necessarily reduce hypertension is irrelevant since Barones explicitly teaches a method of treating hypertension comprising administering a PDE inhibitor such as rolipram with sufficient disclosure for enablement.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
Bbs

BONG-SOOK BAEK
Examiner, Art Unit 1614